Citation:

Abete I, Parra D, Martinez JA. Energy-restricted diets based on a distinct food selection affecting the glycemic index induce different weight loss and oxidative response. *Clin Nutr.* 2008 Aug; 27(4): 545-551.

PubMed ID: 18308431

Study Design:

Randomized controlled trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate the effects of two energy-restricted diets with different food distribution and glycemic index values on weight loss and energy metabolism in the nutritional treatment of obesity.

Inclusion Criteria:

Obese.

Exclusion Criteria:

Subjects with:

- Diabetes, hypertension, liver, renal or hematological disease or other clinical disorders that could interfere with the weight loss process
- Weight change higher than ±3kg within the three months before the start of the study
- Participation in another scientific study up to 90 days before
- Chronic pharmacological therapies, pregnancy, surgical or drug-related obesity treatments
- Alcohol or drug abuse.

Description of Study Protocol:

Recruitment

Potential volunteers were contacted through internal and local advertisements.

Design

- Eight-week randomized trial of two energy-restricted diets with higher or lower glycemic

index (same macronutrient distribution: 53% energy as carbohydrate (CHO) 17% protein and 30% fat)
- The energy restriction was -30% in relation to energy expenditure.

Dietary Intake/Dietary Assessment Methodology

- Three-day weighted food records for information about baseline intake and adherence to prescribed diet
- Diet records were assessed by using the Medisystem software adapted for Spanish foods (Sanocare, Spain) and the glycemic index was calculated using a validated guide.

Intervention

- Subjects were randomly assigned to high- or lower-glycemic index energy-restricted diets. The diets provided the same distribution of macronutrients (53% of energy as CHO, 17% as proteins and 30% as fats). Participants were individually instructed to follow the prescribed dietary regime for eight consecutive weeks by a trained dietician within a strict dietary framework, which was repeated on a three-day rotation basis. Subjects were asked to maintain the same habitual physical activity during the intervention
- Low-glycemic index diet: 84% of CHOs was from pasta and legumes; glycemic index of 40 to 45 units
- High-glycemic index diet: 84% of CHOs was from rice and potatoes; glycemic index of 60 to 65 units.

Statistical Analysis

- Changes in weight loss were evaluated and compared by applying paired parametric T-tests (baseline vs. endpoint) and the repeated measures ANOVA to evaluated the weight loss time course (eight points)
- The Wilcoxon (non-parametric) and paired T-test (parametric) were applied to analyze within groups differences (baseline vs. endpoint) as appropriate
- The student T-test (parametric) and Mann-Whitney U test (non-parametric) were used to analyze between-groups differences (lower vs. higher-glycemic index)
- The Pearson (parametric) or the Spearman (non-parametric) coefficients were used to set up the potential relationships among variables
- A multivariable regression model with no more than three variables based on sample size was applied to describe the observed mitochondrial oxidation changes (dependent variable), considering diet, leptin (adjusted for fat mass) and resting energy expenditure (adjusted for fat free mass) as independent variables.

Data Collection Summary:

Timing of Measurements

- Anthropometry, body composition, energy expenditure, mitochondrial oxidation, blood and 12-hour urine samples were assessed at baseline (day zero) and at the endpoint (day 56)
- Weight loss was monitored weekly by a dietician.

Dependent Variables

- Body weight
- Body mass index (BMI)

- Waist circumference
- Fat mass
- Fat free mass
- Muscle arm area
- Blood pressure
- Total cholesterol (TC)
- HDL and LDL cholesterol
- Triglycerides
- Blood glucose
- Blood insulin, HOMA (homeostatic model assessment) index
- Circulating leptin (adjusted for fat mass)
- Resting energy expenditure.

Independent Variables

- Low-glycemic index diet
- High-glycemic index diet.

Control Variables

- Leptin
- REE.

Description of Actual Data Sample:

- *Initial N:* 32 (14 female, 18 male)
- *Attrition (final N):* 32
- *Mean age:* SD of 36 (seven) years
- *Other relevant demographics:* Mean (SD) BMI of 32.5 (4.3) kg/m^2
- *Anthropometrics:* Both groups had similar characteristics at baseline except for TC, which was higher in the lower glycemic index diet (P=0.014)
- *Location:* Spain.

Summary of Results:

Percent Change (SD) (Eight-week Follow-up vs. baseline) in Measured Variables for the High and Low-glycemic Index Diet Interventions

Variables	Higher Glycemic Index Diet	Lower Glycemic Index Diet	P-value for Difference in % Change
	% Change (N=16)	% Change (N=16)	
Weight (kg)	-5.3 (2.6)*	-7.5 (2.9)*	0.033
Body mass index (kg/m^2)	-5.4 (2.5)*	-7.6 (3.0)*	0.030
Waist circumference (cm)	-6.4 (3.3)*	-6.4 (3.6)*	0.988
Fat mass (kg)	-13.1 (8.5)*	-14.8 (5.8)*	0.552

Fat free mass (kg)	-1.3 (3.9)	3.5 (3.3)*	0.126
Muscle arm area (cm^2)	-2.9 (3.6)*	-4.7 (3.7)*	0.189
Systolic blood pressure (mmHg)	-3.7 (5.3)	-6.5 (8.2)	0.275
Diastolic blood pressure (mmHg)	-5.7 (8.6)*	-7.5 (7.5)	0.551
Total cholesterol (mg per dL)**	-3.5 (10.6)	-14.4 (10.5)	0.010
LDL-cholesterol (mg per dL)	-3.2 (14.3)	-15.9 (16.6)	0.037
HDL-cholesterol (mg per dL)	-5.5 (14.9)	-9.7 (8.1)	0.348
Triglycerides (mg per dL)	5.1 (40.8)	-2.4 (18.0)	0.531
Circulating glucose (mg per dL)	-1.9 (6.3)	-2.2 (5.5)	0.897
Circulating insulin (uUI per ml)	19.7 (58.2)	-15.7 (44.5)	0.085
HOMA index	20.6 (65.8)	-16.5 (47.6)	0.102
Circulating leptin (adjusted for fat mass) (ng per ml)	-21.1 (1.8)*	-22.4 (2.2)*	0.125
Resting energy expenditure (kcal per day)	-6.7 (5.0)*	-6.1 (4.8)*	0.783

*P-value <0.05 for within group change (baseline vs. endpoint).

**TC levels differed between groups at baseline (P=0.014).

Key Findings

- Volunteers consuming the lower glycemic index diet showed a significantly higher weight loss than their counterparts (-5.3±2.6% vs -7.5±2.9%; P=0.032), although the decrease in REE was similar between groups (P=0.783)
- Mitochondrial oxidation was significantly affected by the type of diet (P=0.001), being activated after the lower glycemic index diet (P=0.022)
- One year after the nutritional intervention, weight regain was only statistically significant in the higher GI group (P=0.033).

Author Conclusion:

- Both the high- and low-glycemic index hypocaloric diets induced weight loss, but the effect of the lower glycemic index diet on energy metabolism (REE and mitochondrial oxidation), lipids (TC and LDL cholesterol) and glycemic profiles (insulin and glucose) was improved beyond the expectations associated with the weight lowering, as compared to the higher-glycemic index diet

- A lower-glycemic index diet with a specific food selection (such as legumes or cereals) is able to differentially affect weight losses and to modulate the energy adaptations to the caloric restriction.

Reviewer Comments:

Groups differed in total cholesterol at baseline; small number of subjects; short intervention or follow-up period.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No

3.	**Were study groups comparable?**	No
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	No
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	N/A
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A

5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes

	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	???
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	No
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes